K090130 Page 1/3

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
December 10, 2008

Submitter's Information: 21 CFR 807.92(a)(1)

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APR - 2 2009

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Product Name:	ATMOS S041 Wound™
Common Name:	Powered suction pump
Classification Name:	pump, portable, aspiration (manual or powered) 878.4780, Class II
Product Code:	OMP

Predicate Device: 21 CFR 807. 92(a)(3)

510(k) Number	K061367
Device Name	BlueSky VISTA™ Wound Vacuum System
Applicant	BlueSky Medical Group, Inc. 5924 Balfour Ct., Suite 102 Carlsbad, CA 92008
Regulation Number	878.4780
Classification Product Code	OMP
Decision Date	08/10/2006
Decision	Substantially equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery

Device Description: 21 CFR 807 92(a)(4)

The ATMOS S 041 Wound is a device to remove bodily fluids for wound drainage and can be used by patients over an extended period of time as recommended by a physician. The device has a rechargeable battery and therefore is portable. A microprocessor controlled electronic battery charging unit in the suction device guarantees the safe charging of the battery, and overcharging of the battery.

The ATMOS S 041 Wound itself is not a sterile device but can use disposable (sterile) items from other manufacturers but these items are not a part of the S 041, (e.g. various hose sets, containers, trocars and catheters) which have been designed for the wound drainage.

Indications for Use: 21 CFR 807 92(a)(5)

The ATMOS S041 Wound™ is a suction device intended for aspiration and collection of secretions and body fluids from wounds and is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing. ATMOS S041 is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/neuropathic ulcers
- Venous insufficiency ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Explored fistulas
- Skin flaps and grafts

510(k) Summary of Safety and Effectiveness

Contraindications
The use of the ATMOS S 041 WOUND is contraindicated in the presence of:
- Eschar
- Untreated osteomyelitis
- Malignancy in wound (with exception of palliative care to enhance quality of life)
- Untreated malnutrition
- Exposed arteries, veins or organs
- Necrotic tissue
- Non-enteric unexplored fistulas
- Exposed nerves
- Exposed anastomotic site
- Exposed bone or tendons
- Exposed vasculature

The ATMOS S 041 WOUND is not designed for use with emergency medical services.

Not to be used:
- In non-medical applications
- In presence of combustible or explosive fluids or gases

Technological Characteristics: 21 CFR 807 92(a)(6)

The ATMOS S 041 Wound is a small suction unit. The device is operated by an electromotive membrane pump which is maintenance-free. When it operates, the pump creates a vacuum in the hose system and in the collection jar, with the help of which secretions can be sucked off through the set of hoses. The pump switches off after creation of the vacuum and then switches on again when the vacuum lies below a certain value.

The secretion is collected in a collection jar. A hydrophobic bacterial filter prevents the secretion being inadvertently drawn into the pump head. The device is fitted with a rechargeable battery. A microprocessor controlled electronic charging unit in the suction device guarantees the safe charging of the battery, and thus overcharging of the battery is avoided. The electronic unit prevents overheating of the suction device by a high temperature switch. For the mobile use a carrying strap is available. Useful accessories are a shoulder bag and a device support.

The ATMOS S 041™ device are substantially equivalent to other legally marketed devices in the United States and functions in a manner similar and is intended for the same use as the predicate device.

Brief summary of Non-clinical Tests and Results

Software verification and product validation tests were performed and meet the acceptance criterion. The ATMOS S 041™ device have been designed and tested to applicable safety standards (see below) and does not raise any new issues of safety, efficacy, or performance of the product.

Number of standard	Std Date	Title of standard
ISO 10993-1:1998	1998	Biological Compatibility of medical devices – Part 1: Evaluation and Testing[1]
EN 60601-1-2 (2001)	2001	Medical electrical equipment -- Part 1-2: General requirements for safety -Collateral standard: Electromagnetic compatibility - Requirements and tests
EN ISO 61000-3-2 (2000):	2000	Electromagnetic compatibility - Part 3-2: Limits - Limits for Harmonic current emissions (equipment input current < 16A per phase).
EN ISO 61000-3-3 (1995) + A1 (2001)	1995 2001	Electromagnetic compatibility - Part 3: Limits - Section 3: Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current < 16A.

[1] Result of evaluation: for ATMOS S 041 Wound: No biocompatibility tests are needed because device does not have parts that would normally touch patient.

510(k) Summary of Safety and Effectiveness

Number of standard	Std Date	Title of standard
CEN EN 980:1996+A1:1999+A2:2001	1999 2001	Graphical symbols for use in the labeling of medical devices
EN ISO 14971	03/2001	Medical devices – application of risk management to medical devices
IEC 60601-1	1998, 1991, 1995	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) for the ATMOS S 041™ device contains adequate information and data to enable FDA to determine substantial equivalence to the predicate device. The device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2009

ATMOS, Inc.
% TUV Rheinland of North America, Inc.
Tamas Borsai
12 Commerce Road
Newton, Connecticut 06470

Re: K090130
Trade/Device Name: ATMOS S041Wound™
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: OMP
Dated: March 19, 2009
Received: March 23, 2009

Dear Tamas Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090130

Device Name: ATMOS S041 Wound™

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

David Krause for NXM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090130